10 Bioinformatics Materials and Issue of Patentability (*)

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Bioinformatics is an important field of biotechnology. With the advancement of bioinformatics, the conventional laboratory-based biotechnology has been transformed into a computer-based science. Bioinformatics is able to bring new inventions which are far beyond the scope of conventional laboratory based biotechnology. Bioinformatics has brought various significant advancements in biotechnology field. It is an important area of invention which directly effects human health and other areas of human life. This research addresses the issue related to the patentability of bioinformatics materials. On this issue, different jurisdictions have different approach. Many jurisdictions have not even touched this subject matter. Further research, investment, and development in bioinformatics field will depend on its ability to obtain patent protection. This research critically examines the patentable aspects of bioinformatics materials, i. e., biological sequences, sequences database, and software. It surveys related patent laws and practices of Japan, the US, Europe, Canada and Australia, and it analyzes whether bioinformatics innovations are protected by patent in these jurisdictions; similarity and contradictions of patentability aspects of bioinformatics materials between different jurisdictions; its interrelationship with the open source policy; and the issues of harmonization of this subject matter.

Ⅰ General Introduction to Bioinformatics

There is no single and well accepted definition of Bioinformatics. There is debate on the scope of its use within the biological and computer sciences. To some, bioinformatics and computational biology are same, and both are defined as any use of computers for processing any biological-derived information, i. e., DNA sequences, breast x-rays and other. To them, bioinformatics is a synonym for computational molecular biology, i.e., any use of computers to characterize the molecular components of living things.[1] To others, bioinformatics relates to the computer science, i.e., information science and/or information technology, and they emphasize the information contained within the biological data.[2] However, in practice, it has been accepted as a combination of both sciences.

Biologists use computer to store, retrieve, analyze or predict the composition or the structure of biomolecules. Biomolecules include genetic material – nucleic acids – the products of genes: proteins. [3] Fredj Tekaia defines bioinformatics as "The mathematical, statistical and computing methods that aim to solve biological problems using DNA and amino acid sequences and related information."[4]

The National Institute of Health (NIH) defines "Bioinformatics" as: "Research, development, or application of computational tools and approaches for expanding the use of biological, medical, behavioral or health data, including those to acquire, store, organize, archive, analyze, or visualize such data."[5] Brian M. Gaff, Ralph A. Loren, and Gareth Dickon define bioinformatics as, "…The use of information technology in the analysis and organization of data relating to biology."[6]

Bioinformatics can be used in various fields, i. e., molecular medicine, personalized medicine, preventive medicine, gene therapy, drug development, crop improvement, insect resistance, improve nutritional quality, and many other.[7] "Every disease has a genetic component. … The completion of the human genome means that we can search for the genes directly associated with different diseases and begin to understand the molecular basis of these diseases more clearly. This new knowledge of the molecular mechanisms of disease will enable better treatments, cures and even preventative tests to be developed."[8] "The potential for using

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genes themselves to treat disease may become a reality. Gene therapy is the approach used to treat, cure or even prevent disease by changing the expression of a persons' genes."[9] "The arrival of the complete genome sequences and their potential to provide a greater insight into the microbial world and its capacities could have broad and far reaching implications for environment, health, energy and industrial applications."[10]

Ⅱ Bioinformatics in the US, Canada, EU, Japan and Australia

In general, bioinformatics materials include biological sequences (DNA, RNA, Proteins), sequences database and software. Biological sequences are generally stored in database and computer software analyzes these biological sequences database. In the following paragraphs, this research examines whether biological sequences, sequences database and software are protected by patent or not in the US, Canada, EU, Japan and Australia.

1 Biological Sequences (DNA, RNA, Proteins)

For a long time, there is ongoing issue of patentability of modern biotechnology. The doubt has been expressed on the applicability of traditional principles of patentability to a new and different form of technology.[11] DNA is not a product, but carries information.[12] However for the purpose of patentability, DNA is considered analogous to chemical compounds.[13] There is also the insufficiency of written forms of description which is required to ensure a third party's ability to repeat an innovation.[14] Physical deposit of lower life forms in depositing agency is considered to meet the requirements of enablement and disclosure.[15] Justin Pila further writes, "Accommodating modern biotechnology within the patent system on the basis of its equivalence to new chemical compounds is problematic because, at a fundamental level, no such equivalence exists. However, accommodating modern biotechnology within the patent system as information is also problematic because information, according to traditional patent jurisprudence, is not a subject matter that patent law protects."[16] There is also a question of lacking of novelty because of their prior existence and lacking of inventiveness because of their derivation from natural conditions.[17] Patenting modern biotechnological invention has been criticized as unethical, immoral, or contrary to public policy, and also it gives inappropriate monopolies to living organisms.[18]

Jurisdictions which allow patenting to DNA have also no similar standing. In the US, after 30 years of granting patents to genes, the question of the patentability of genes was considered again by the US Supreme Court. On June 13, 2013, the US Supreme Court ruled that, "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."[19] Canada has been granting patent to DNA. In 2002, the Supreme Court of Canada in Harvard College v. Canada (Commissioner of Patents) case ruled that higher life-forms of animals and plants were not patentable subject matter while microorganisms (cells and genes) were patentable.[20] In Europe, the patentability of isolated genes is expressly accepted in European law after the implementation of the Directive on the Legal Protection of Biotechnological Inventions (EU Biotechnology Directive) in 1998.[21] In Japan, the Japanese Patent Act defines invention as a "highly advanced creation of technical ideas utilizing the laws of nature."[22] The "technical idea" must have a certain degree of concreteness, operatives or repetitiveness and may not simply be a discovery of a "law of nature".[23] Biotechnological inventions including isolated DNA are patentable in Japan.[24] In Australia, "The building blocks of living matter, such as DNA and genes (including human DNA and genes) which have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a definite industrial use"[25] are not deemed to be a discovery.[26] Whether human gene (isolated DNA) is patentable or not has been under consideration before the Supreme Court of Australia. However, after the Myriad decision in 2013,[27] the standard of isolated DNA patenting has been changed and it is no more patentable subject matter in the US. We will see what course the EU and Japan will take on this patentable issue in the near future.

2 Sequences Database

Bioinformatics databases in general are sequence databases (DNA, RNA and protein sequences). In addition to the sequence database, there are databases on gene mapping, protein structure and literature citations.[28] There is no

sui-generis law on database protection in the US, Canada, Japan and Australia, but the EU has the Directive on the Legal Protection of Databases.[29] The database law (sui –generis system) protects bioinformatics data or the contents of the database. To qualify for database law protection, it needs to meet the requirements of qualitative or quantitative investment of a substantive nature while obtaining the data or verifying the data or presentation of the contents of the database. This European database protection is available only to EU citizen. [30] Copyright cannot provide direct protection to bioinformatics database, but compilation of such date can be subject of copyright protection.[31]

3 Software

It is the computer software which analyzes biological sequence database and invent new medicine or crops or plants or solve biological problems. Biologists use computer to store, retrieve, analyze or predict the composition or the structure of biomolecules. Biomolecules include genetic material – nucleic acids – the products of genes: proteins.[32] It is important to identify the function of a gene to develop useful products such as pharmaceutical products. To identify the function of a gene, we need to analyze DNA, and the techniques for analyzing DNA include bioinformatics using information processing by computer among other.[33] Hence, the patent protection to bioinformatics software is important for further advancement of bioinformatics.

In the US, computer program as such is not excluded from patentable subject matter by law. Computer software is patentable if it meets the statutory requirements for all patentable inventions.[34] In 1998, the US Federal Circuit Court of Appeals in its decision in the *State Street Bank & Trust Co. v. Signature Financial Group Inc*.[35] case ruled that mathematic algorithms was patentable if they produce a "useful, concrete and tangible result."[36] In 2008, the US Federal Court of Appeals changed its previous test "useful, concrete and tangible result" and held in its decision in the *In re Bilski*[37] case that in order to be eligible patent subject matter the claims must either tie a business method to a machine, or represent a transformation (e.g., the machine-or-transformation test).[38] In 2010, the US Supreme Court in *Bilski v. Kappos*[39] case held that the machine or transformation test is a valuable clue to the question of process patent eligibility but this is not an exclusive test for process or method patents.[40]

In Canada, computer software is patentable. It needs to meet statutory requirements of patentability, i.e., novelty, utility and non-obviousness and the software must be stored on a physical memory to obtain patent protection. Basically, the computer software needs to provide a "technological solution to a technological problem" to be considered as patentable. European approach towards patenting of software invention is different than the US. Computer program "as such" are not patentable in Europe. To be eligible for patent protection in Europe, a computer implemented invention should solve a technical problem in a novel and non-obvious manner. 41 In Japan, computer program is patentable. For computer program, copyright protection is available for the code. For method of processing, patent protection is available for new innovations if it meets patent requirements. For patent protection being granted, software program is required to be a creation of technical ideas "utilizing a law of nature." According to Standard for Software, this requirement is typically met by "concretely realizing the information processing performed by the software by using hardware resources." Bioinformatics generally involves information processing by using hardware resources. In Australia, pure or abstract methods of doing business are not considered to be patentable, but if the method is implemented using a computer, it is patentable. Although they may have different test methods, the US, Canada, Japan, EU and Australia have been granting patent to bioinformatics software.

Ⅲ Similarity and Contradictions Between Jurisdictions and Requirement of International Harmonization

Regarding granting patent protection to the bioinformatics materials, there are some similarity and some contradictory provisions among the patent laws of the US, Canada, EU, Japan and Australia. Their patent laws and practices on gene patenting differ to each other. The US, Canadian and Japan patent laws have neither written provision on DNA patenting nor any provision of exclusion from patentability. In the US, gene was granted patent protection for

the first time by court decision.[42] However, in 2013, the US Supreme Court in Myriad case ruled that, "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, …."[43] The current US position does not allow granting patent to isolated DNA. Whereas the EU has written legal position and says that isolated DNA is patentable.

It is furthermore related to DNA patenting, the EU and Australian patent laws have provision of exclusion. The European Patent Convention states, "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body" are excluded from the patentable subject matter.[44] The Australian Patent Act states, "human beings, and the biological processes for their generation" are excluded from patentability.[45] Whereas the US, Japan and Canadian patent laws have no such written provision of exclusion from patentability.

The EU and Japan have provision of public order and moral where any DNA related invention contrary to public order and moral are considered as non-patentable. Australian patent law has also such provision where new invention the "use of which would be contrary to law" is non-patentable.[46] Whereas the US and Canadian patent laws have no such provision of public order or moral.

In Europe, software inventions are treated differently than in the US. Software inventions are excluded from patentability if they are computer programs "as such." For the software patentability, inventor needs to claim more than just a program for a computer and the invention needs to be tied to hardware.[47] In the US, there is no legal provision which excludes patentability of computer program as such. Computer software is patentable if it meets the statutory requirements for all patentable inventions.[48] Japan, Canada, and Australia have also been granting patent to bioinformatics software in different ground which we have already discussed.

In addition, there is no similarity of constitutional authority in making patent law in these jurisdictions. In Japanese Constitution, there is no provision of authorizing legislative power to Legislative body to make patent law explicitly. The US Constitution authorizes patent law making power to Congress. The Constitution of Canada authorizes patent law making legislative power to the Parliament.[49] The Australian Constitution authorizes patent law making legislative power to the Parliament.[50] The European Patent Convention which is the authority to grant patent to inventions is based on treaty and not on any constitution as such.

On the issue of harmonization of patent laws relating to biotechnological inventions, there is criticism of any attempt at harmonizing patent law. Justine Pila writes, "The problems created for patent law by modern biotechnology are far from resolved."[51] She further writes, "The nature of those problems is such that formal attempts at harmonizing patent law can only make them worse."[52] The issue of the harmonization of biotech patent law seems uncertain, because of the controversy surrounding the biotech patenting.[53] Even the European Patent Convention (EPC) could not achieve successful harmonization in Europe whereas the EPC was aimed to harmonize patent law all over Europe. Each member countries of different values and interests have applied the provisions of EPC differently.[54] For example, EPC has provision of DNA patentability whereas French law does not grant patent to DNA.

On top of that the issue of international harmonization of patent law is not supported by international law as such. In 1988, regarding the patentability of DNA sequences, the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and the Japanese patent Office (JPO) issued a statement:

> "Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds."[55]

However, the position of this statement has been changed after the decision of the US Supreme Court in *Myriad case* in 2013. Now the latest US version considers isolated DNA as a discovery and not an invention. The approach of biotech patenting and lack of conformity of fundamental norm among them creates doubt of harmonization.[56]

There is no international law obligation to

harmonize patent laws among various jurisdictions. It is also presumed that a state would perform its international obligations in good faith. Infringement of the international obligation is not to be presumed.[57] International law is indifferent as to how a state meets its international obligations.[58]

The WTO Agreement and the TRIPS Agreement have provision of compliance which is different than international harmonization. The WTO Agreement states:

> "Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements."[59]

The TRIPS Agreement states:

> "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, … Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[60]

Ⅳ Policy towards Openness

The science of genomics has been growing up with different outlook than any other fields of knowledge. Openness is the main operating principle in the field of genomics. All genomic data are freely available online. The spirit of the scientists who are working in this field have strong urge to facilitate their invention freely to others. Richard Stallman had epitomized the free software movement, a vision of making software development a culturally enriching experience.[61] In the free software movement, software source code is distributed in an open and free manner to further modify and improve software.[62] The "Creative Commons" movement" of Japan is similar to the "Open Source" movement of America or Europe.[63]

Ⅴ Conclusion

Bioinformatics has brought revolutionary changes in the fields of medicine, agricultural crops, plants and others. The scientists who are working in this field have less profit motive and more motive of contributing to the society by offering their works or inventions freely. The spirit of scientists has impacted this field differently. The bioinformatics materials can be protected by using patents, copyright and trade secrets. Among available protections, patent protection is the broadest protection. Bioinformatics software patent is one of the difficult protections to obtain. Trade secrets may be able to protect sequences database, but due to special nature of sequence database which are publicly available, trade secrets law is not effective to provide protection to sequences database. Copyright law protects original expression and it does not protect ideas or functionality of software programs. Copyright may protect the source code of the computer software program, but if such code has been rewritten and is no longer similar to the original code, copyright protection will not be available.

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1 http://bioinformatics.org/wiki/Bioinformatics (visited Dec. 16, 2013).
2 *Ibid.*
3 *Ibid.*
4 Fredj Tekaia at the Institute Pasteur available at http://bioinformatics.org/wiki/Bioinformatics (visited Dec. 16, 2013).
5 http://www.bisti.nih.gov/docs/CompuBioDef.pdf (visited Dec. 16, 2013).
6 Brian M. Gaff, Ralph A. Loren, and Gareth Dickon, *Protecting Bioinformatics as Intellectual Property,* Computer and the Law, published by the IEEE Computer Society, Jan. 2013 at 15 [Gaff et al].
7 Bioinformatics – Applications Areas, Bioinformatics Resource Portal
Available at
http://bioinformaticstools.webs.com/application.htm
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8 *Ibid.*
9 *Ibid.*
10 *Ibid.*
11 Justine Pila, *Bound Futures: Patent Law and Modern Biotechnology*, 9 B. U. J. Sci. & Tech. L. 326 2003 at 328 [Pila].
12 *Ibid* at 337.
13 *Ibid* at 334.
14 *Ibid* at 336.
15 *Ibid* at 336.
16 *Ibid* at 338.
17 *Ibid* at footnote number 71.
18 *Ibid* at 360.
19 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 569 U. S. at Pp. 10-18 (2013) [*Myriad*].
20 [2002] 4 SCR 45 [*Harvard College*].
21 Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, 21 & art. 17 [*The Directive 98/44/EC*].
22 Government of Japan (1959), Patent Act, Act No. 121 of 1959, latest revision Act No. 109 of 2006 at art. 2(1) [*Patent Act*]. English translation, available at http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf.

[23] Kitagawa, Z. (ed.) (2006), *Doing Business in Japan*, Chapter 16 Intellectual Property, Vol. 1, Newark, NJ: LexisNexis, §16.02[2] at 16-8.

[24] JPO (2005), *Examination Guidelines for Patent and Utility Model*, Part VII: Examination Guidelines for Inventions in Specific Fields, Chapter 2 Biological Inventions, Chapter 3 Medicinal Inventions, December 28, 2000, Latest Revision November 2005, English Translation, available at http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm.

[25] Australian Government, Australian Law Reform Commission, Patentability of Genetic Materials and Technologies, para 6.34 [Australian Law Reform Commission, Patentability], Available at http://www.alrc.gov.au/publications/6-patentability-genetic-materials-and-technologies/patentable-subject-matter (visited Feb. 10, 2014).

[26] *Ibid*.

[27] *Myriad, supra* note 19.

[28] Junli Chang and Xuezhong Zhu, "Bioinformatics Databases: Intellectual Property Protection Strategy," Journal of Intellectual Property Rights, Vol. 15, November 2010, p. 448 [Chang and Zhu].

[29] Directive 96/9/EC, 1996 O.J. (L 77) 20 [*Directive 96/9/EC*].

[30] Chang and Zhu*, supra* note 28 at 448.

[31] Elizabeth Howard and Gabriel Ramsey, "Bioinformatics Databases: Questions of Copyright," BioPharm International, Nov. 2002, p. 46 [Howard and Ramsey].

[32] Caroline McCubbin, "Legal issues in bioinformatics," Journal of Commercial Biotechnology, Vil 9. No 3. at 250, March 2003 [McCubbin].

[33] *Ibid* at 208.

[34] Charles Vorndran & Robert L. Florence, "Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences," (2002) 42:1 IDEA 93 at 108 [Vorndran and Florence].

[35] 149 F. 3d 1368, 47 U. S. P. Q. 2d 1596 (U. S. Fed. Cir. 1998).

[36] Vorndran and Florence, supra note 34 at 1374.

[37] *In re Bilski*. 545 F.3d at 961-2 (Fed. Cir. 2008).

[38] Karen Durell, Miller Thomson LLP, "Still Waiting to Resolve the Fate of Business Method Patents," Information & Technology Law Newsletter (Info. Tech. Nws. 2010-04) August 2010, (J. Fraser Mann, Editor) [Durell and Thomson].

[39] *Bilski v. Kappos*. U.S., No. 08-964 (6/28/10).

[40] Isabelle Huys, Geertrui Van Overwalle and Gert Matthijs, "Gene and genetic diagnostic method patent claims: a comparison under current European and US patent law," European Journal of Human Genetics (2011) 19, 1104- 1107, at 1106 [*Huys et al*].

[41] European law and practice, European Patent Office, Munich, Germany, 2013 at page 15 [European Patent Office]. Available at www.epo.org.

[42] 447 U. S. 303 (U. S. Sup. Ct., 1980) [*Chakrabarty*].

[43] *Myriad, supra* note 19 at Pp. 10-18.

[44] Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199 at art. 52(4) [*The European Patent Convention,* 1973].

[45] *Patents Act 1990* (Cth) s 18(2).

[46] *Patents Act 1990* (Cth) ss 18(2), 50(1)(a), 101B(2)(c), (d).

[47] Gaff et al, *supra* note 6 at 16.

[48] Vorndran and Florence, *supra* note 34 at 108.

[49] Article 91 of the Constitution Acts, 1867 to 1982.

[50] *Australian Constitution* s 51(xviii).

[51] Pila, *supra* note 11 at 327.

[52] *Ibid*.

[53] Pila, *ibid* at 369.

[54] Pila*, ibid* at footnote number 150. For example, the U. K. Courts of Appeal applied narrow interpretation of the EPC Art. 52(2) in *Genentech, Inc. v. Wellcome Found.*, 1989 R.P.C. 147 (Eng. C.A. 1988).

[55] 'Trilateral Co-operation of the US, European and Japanese Patent Offices' (1988) 7 Biotechnology Law Review 159, 163 cited in R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 Bio-Science Law Review 71. See Australian Law Reform Commission, Genes and Ingenuity: Gene patenting and human health (ALRC 99) (Government of Australia, June 2004) [Australian Law Reform Commission], online: http://www.austlii.edu.au/au/other/alrc/publications/reports/99/ (visited on Feb. 6, 2014).

[56] Pila, *supra* note 11 at 377.

[57] Kwan Kiat Sim, *Rethinking the mandatory/discretionary legislation distinction in WTO jurisprudence*, World Trade Review (2003), Vol. 2, Issue 1, page 59. *See* Article 26 of the Vienna Convention of the Law of Treaties 1969.

[58] OPPENHEIM'S INTERNATIONAL LAW (Robert Jennings and Arthur Watts ed., 1992, Longman), Section 21 at 83.

[59] The Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I. L. M. 1144 (1994) at art. XVI, para 4 [hereinafter WTO Agreement].

[60] The Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I. L. M. 1197 (1994) at art. 1(1) [hereinafter TRIPS Agreement].

[61] Brian Fitzgerald, INTELLECTUAL PROPERTY SYMPOSIUM: Theoretical Underpinning of Intellectual Property: "I am a Pragmatist But Theory is my Rhetoric," *16 Can. J.L. & Juris. 179, July 2003* at page 188.

[62] *Ibid*.

[63] Interview with Professor Yoshiyuki Tamura, Director, Research Institute for Information Law & Policy, School of Law, Hokkaido University, Japan on January 25, 2014.